ALFOODACT 031-2010 Expansion of ALFOODACT 004 and 025-2010 McNeil Consumer Healthcare Recall of OTC Products

Date Issued: July 9, 2010

Deliver immediately to the following Army, Navy, Air Force, Marine Corps, Coast Guard, or other Activities as appropriate:

Regional Veterinary Commanders;

Public Health Officer/Medical Food Inspection Personnel;

Regional Veterinary Laboratory Consultant;

Medical/Veterinary Authority;

Preventive Medicine Officer;

TISA Officer;

Food Service Officer/Troop Support Warehouse Manager;

Club Managers;

Defense Commissary Agency Staff Veterinarian;

Defense Commissary Agency Regional Director;

Defense Commissary Agency Central Distribution Centers;

Commissary Officer;

COCOM Staff Veterinarian;

HQ, AAFES, Staff Veterinarian;

HQ, AAFES-Europe, Staff Veterinarian;

Exchange System Manager;

Restaurant Officer;

Nutritional Medicine Services;

NAVSUP/Staff Veterinarian;

RESALEACT/RESALEACT DET;

Public Information Officer/Public Affairs Officer;
Chief, MWR;

DSSC/Issue Commissary Officer;

Supply Office;

Defense Supply Center Philadelphia-Europe;

Defense Supply Center Philadelphia-Pacific;

DLA Depots and Supply Points/Defense Subsistence Officers;

Defense Subsistence Storage Facilities;

US Army Europe & Europe Regional Veterinary Command;

Assistant Administrator (AA) and Deputy AA, Office of Public Health Science, FSIS;

AA and Deputy AA, Office of Field Operations, FSIS;

1. REFERENCES:

a. DLAR 4155.26/AR 40-660/NAVSUPINST 10110.8c/AFI 48-116/MCO 10110.38c, DOD Hazardous Food & Nonprescription Drug Recall System.

b. Allied Communications Publication 121, US SUPP-1 (f).

2. BACKGROUND:

McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc., is recalling 21 lots of over-the-counter medicines as an addition to the products included in ALFOODACT 004-2010 and 025-2010. The lots involved, listed below, are sold in the United States, Fiji, Guatemala, Dominican Republic, Puerto Rico, Trinidad & Tobago, and Jamaica. This action is a follow-up to a product recall McNeil Consumer Healthcare originally announced on January 15, 2010, which was initiated following consumer complaints of a musty or moldy odor, which has been linked to the presence of trace amounts of a chemical called 2,4,6-tribromoanisole (TBA). The risk of serious adverse medical events is remote. These lots are being added to the list of recalled products as a precautionary measure after a continuing internal review determined that some packaging materials used in the lots had been shipped and stored on the same type of wooden pallet that was tied to the presence of TBA in earlier recalled lots. All lots involved in the recall were produced before the January 15, 2010 recall, after which McNeil stopped accepting shipments of materials from its suppliers on that type of pallet.

3. PRODUCTION DATES/IDENTIFYING CODES:

Product Name// Product Form// Lot Number// NDC Number// UPC Code.

BENADRYL(r) ALLERGY ULTRATAB(tm)// TABLETS 100 count// ABA567// 312547170338.

BENADRYL(r) ALLERGY ULTRATAB(tm)// TABLETS 100 count// ABA574// 312547170338.

CHILDREN'S TYLENOL(r) MELTAWAYS// BUBBLEGUM 30 count// ABA544// 300450519306.

MOTRIN(r) IB// CAPLET 24 count// ACA003// 300450481030.

MOTRIN(r) IB //CAPLET bonus pack 50+25 count// ACA002// 300450481764.

MOTRIN(r) IB// TABLET 100 count// AFA060// 300450463043.

TYLENOL(r), Extra Strength // EZ TABLET 225 count// ASA206// 300450422378.

TYLENOL(r), Extra Strength //EZ TABLET 50 count// ABA005// 300450422507.

TYLENOL(r), Extra Strength// COOL CAPLET 24 count// ABA566// 300450444240.

TYLENOL(r), Extra Strength// CAPLET bonus pack 24+12 count// ACA025// 300450444318.

TYLENOL(r), Extra Strength // CAPLET 50 count// AFA018// 300450449078.

TYLENOL(r), Extra Strength //CAPLET 50 (included in Day/Night Pack)// ABA168// 300450444530.

TYLENOL(r), Day & Night Value Pack//(contains Extra Strength CAPLET 50 count Lot # ABA168 & UPC 300450444530)// AEC005// 300450527103.

TYLENOL(r), Day & Night Value Pack//(contains Extra Strength CAPLET 50 count Lot # ABA168 & UPC 300450444530)// AFC005// 300450527103.

TYLENOL(r), Day & Night Value Pack//(contains Extra Strength CAPLET 50 count Lot # ABA168 & UPC 300450444530)// ADC002// 300450527103.

TYLENOL(r), Extra Strength RAPID RELEASE //GELCAP 24 count// ACA024// 300450488244.

TYLENOL(r), Extra Strength RAPID RELEASE //GELCAP 225 count// AJA119// 300450488251.

TYLENOL(r) PM// CAPLET 24 count// ACA005// 300450482242.

TYLENOL(r) PM //CAPLET 24 count// ADA259// 300450482242.

TYLENOL(r) PM //GELTAB 50 count// AFA100// 300450176509.

TYLENOL(r) PM RAPID RELEASE //GELCAP 20 count// ACA004// 300450244208.

The product lot numbers for the recalled products can be found on the side of the bottle label.

4. MANUFACTURER/DISTRIBUTOR:

McNeil Consumer Healthcare
Division of McNEIL-PPC, Inc

5. DISTRIBUTION: U.S. Nationwide; Fiji, Guatemala, Dominican Republic, Puerto Rico, Trinidad & Tobago, and Jamaica.

6. REASON FOR ACTION: Presence of trace amounts of a chemical called 2,4,6-tribromoanisole.

7. INSTRUCTIONS AND ADDITIONAL INFORMATION FOR MESSAGE RECIPIENTS:

a. Immediately inventory stocks to identify the above items and secure in a "Medical Hold" status to provide assurance of no further issue/sale/use. POSITIVE FINDINGS should be reported to Accountable Officers/Vendor Representatives of that facility. Accountable Officer/Agency representatives/Buyers/Contracting Officers should seek refund/credit/replacement through the normal distribution channel with which the product was received (i.e. Distribution Centers, Prime Vendors, or Manufacturers).

b. Ships at sea are authorized to destroy or dispose of recalled products at their discretion. Documentation for the number of pounds and cases, and any additional pertinent information must be signed by the Accountable Officer and is required for the purpose of recouping to the government the cost of the product involved. In order to get credit please use a SF 364 and forward to your supporting FISC and copy furnished to NAVSUP 51. Your supporting FISC should forward to the account manager at DSCP. The form should include the number of the recall authorizing the survey action. Home ported ships/galleys will utilize DD form 1149 to transfer w/ reimbursement to the PV. The PV will submit credit invoice to the account manager at DSCP.

c. DSCP Subsistence Prime Vendors must report POSITIVE and NEGATIVE RESPONSES directly to the their DSCP Contracting Officer with a courtesy copy to the Consumer Safety Officer (dscpconssafofc@dla.mil).

d. DeCA, AAFES, MWR, VA, MCCS, or other non-DSCP agencies SHOULD NOT respond to DSCP Consumer Safety Officer. These agencies should report POSITIVE and NEGATIVE responses in accordance with their agency recall policies.

e. When corresponding with DSCP concerning this message please include this message's subject in your subject line.

8. The Point of Contact for this ALFOODACT message is COL John C. Smith, DSCP Veterinary Advisor at DSCP-FTW. VOICE, DSN: 444-8461, Commercial (215) 737-8461, or by FAX, DSN: 444-7526, or Commercial,

(215) 737-7526, email dscpconssafofc@dla.mil.

9. Individuals or groups that would like to receive recall messages electronically can forward their email address to dscpconssafofc@dla.mil, with "add to list" in the subject line. To be removed from the list place "remove from list" in the subject line.

10. Previous recalls and frequently asked questions are available at the following web site: https://www.dscp.dla.mil/subs/fso/alfood/alfood.asp. The navigation tool to the left allows you to also view DSCP Alerts and Archived Vendor Recalls.